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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,331

03/19/2004

Jonathan F. Smith

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PO BOX 37428
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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

09/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,331	Applicant(s) SMITH ET AL.	
	Examiner Benjamin P. Blumel	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,15,18,37-47 and 53-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-14, 16, 17, 19-36, 48-52 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice To Comply</u> . |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/23/04, 9/27/04
11/24/04, 3/31/05, 11/03/05 & 5/4/07 .

DETAILED ACTION

Examiner's Amendment

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 37-59, starting on page 65 of the filed claims from March 19, 2004 have been renumbered 38-60.

Election/Restrictions

Applicant's election with traverse of Invention I and the requested species in the reply filed on July 2, 2007 is acknowledged. The traversal is on the ground(s) that no search burden would exist since the species are limiting in scope. This is not found persuasive because the species of **Groups B-H** are distinct species because each species has distinct properties based on chemical, physical and/or functional characteristics. For example, the plant IRES sites are distinct from mammalian virus IRES sites, the while the viruses of claims 11-14 are grouped from into the same genus, each one is distinct based on their genomes and areas of isolation (i.e. WEE, EEE and VEE). However, based on applicant's remarks, the species election for a specific non-structural protein, **Group A**, is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 7, 8, 15, 18, 20, 22, 37-47 and 53-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 2, 2007.

Claims 1-6, 9-14, 16, 17, 19, 21, 23-36, 48-52 and 58-60 are examined on the merits.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 9/23, 9/27 and 11/24 of 2004, 3/31 and 11/03 of 2005 and 5/4, 9/11 of 2007 were filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Objections

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification is objected to because pages 26, 27, 35, 36, 39, 41, 42 and 48 do not contain specific SEQ ID NOs:.

Applicants must comply with the sequence rules in order to effect a complete response to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 11-14, 16, 23-28, 33 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Polo et al. (US 2003/0148262 A1).

The claimed invention is drawn to a vaccine of a plurality of VEE particles with a recombinant alphavirus RNA replicon comprising a 5' alphavirus replication recognition sequence, a nucleic acid sequence encoding an alphavirus nonstructural protein (nsp), at least one subgenomic promoter, at least one IRES element, at least one heterologous nucleic acid and a 3' alphavirus replication recognition sequence. The nonstructural protein can be nsp 1, 2, 3 and 4 encoded by one nucleic acid or nsp 1-3 and nsp 4 can be encoded by separate sequences. The recombinant nucleic acid also contains a packaging signal. For purposes of examination, the order of inserted sequences are not dictated by the order in which each is listed in claim 1, see 35 U.S.C. 112 Rejection below. The recombinant replicon also contains attenuating mutations and the alphavirus particles are infectious, but replication defective.

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Polo et al. teach generating alphavirus RNA replicon vectors comprising 5' CSE, nucleic acid sequences for nsp 1-4, and 3' CSE. In addition, Polo et al. teach including one or more subgenomic promoters and/or IRES elements in the replicon in order to express one or more heterologous proteins. Polo et al. also teach modifying certain embodiments of the recombinant replicon (i.e. promoters) in order to increase or decrease viral transcription of certain fragments. Polo et al. also teach mixtures of alphavirus particles comprising the alphavirus replicon as part of a vaccine. Polo et al. discuss various alphaviruses as a basis for this alphavirus replicon, such as VEE. While Polo et al. does not specifically state that these particles are infectious-defective, the products taught by Polo et al. would inherently have these characteristics since there does not appear to be any differences between what is being claimed and what is taught by Polo et al. Therefore, Polo et al. anticipates the claimed invention.

Claims 48 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubensky et al. (US 6,426,196 B1).

The claimed invention is drawn to a recombinant nucleic acid comprising a 5' alphavirus replication recognition sequence, an alphavirus subgenomic promoter, an IRES element, a nucleic acid encoding one or more alphavirus structural proteins and a 3' alphavirus replication recognition sequence. The recombinant nucleic acid also contains a packaging signal and it is located in a cell. For purposes of examination, the order of inserted sequences are not dictated by the order in which each is listed in claim 48, see 35 U.S.C. 112 Rejection below.

Dubensky et al. teach a recombinant alphavirus replicon, comprising a 5' replication sequence (CSE), a subgenomic promoter, an IRES, a structural protein and a 3' CSE. Dubensky

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et al. also teach the use of packaging signals with the recombinant alphavirus replicon and culturing the alphavirus replicon in cells. Therefore, Dubenksy et al. anticipates the claimed invention.

Claims 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Polo et al. (US 2003/0148262 A1).

The claimed invention is drawn to a recombinant nucleic acid comprising a first nucleic acid sequence of a 5' alphavirus replication recognition sequence, a second nucleic acid sequence encoding an alphavirus nonstructural protein (nsp), a first subgenomic promoter, a first IRES element, at least one heterologous nucleic acid and a 3' alphavirus replication recognition sequence. The recombinant nucleic acid also contains a packaging signal. For purposes of examination, the order of inserted sequences are not dictated by the order in which each is listed in claim 58, see 35 U.S.C. 112 Rejection below.

Polo et al. teach generating alphavirus replicon vectors comprising 5' CSE, nucleic acid sequences for nsp 1-4, and 3' CSE. In addition, Polo et al. teach including one or more subgenomic promoters and/or IRES elements in the replicon in order to express one or more heterologous proteins. Polo et al. also utilize packaging signals in their constructs. Therefore, Polo et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 9, 10, 16, 19, 21, 29-32, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polo et al. as applied to claims 1-3, 5, 6, 11-14, 16, 23-28, 33 and 34 above, and further in view of Chappell et al. (PNAS, 2000), Martinez-Salas et al. (Journal of General Virology, 2001) and Johnston et al. (US 2001/0016199 A1).

One of the applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

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accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claimed invention as discussed above is also drawn to attenuated alphavirus particles with replicons that express alphavirus structural proteins, have spacer sequences upstream of mammalian IRES elements and that at least 10% of the translation of the gene product from the heterologous sequence is controlled by the activity of the IRES element. In addition, the spacer sequence is between 25-7500 nucleotides in length.

The teachings of Polo et al. are discussed above, however, Polo et al. do not teach using a spacer upstream of the IRES element, the specific percentage of control that the IRES element has on the translation of the heterologous sequence, the specific use of mammalian virus IRES elements, an attenuated alphavirus particle.

Chappell et al. teach the use of spacer lengths (9, 27 and 54 bases) upstream of IRES elements in order to increase protein expression.

Martinez-Salas et al. teach IRES elements from various mammalian viruses, such as Poliovirus, Murine leukemia virus and Simian immunodeficiency virus and their use in expression proteins.

Johnston et al. teach alphavirus RNA molecules expressing alphavirus non-structural and structural proteins. In addition, Johnston et al. teach mutating various amino acids within any nsp resulting in an attenuated phenotype.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Polo et al. in order to express alphavirus replicons that express alphavirus

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structural proteins, have spacer sequences upstream of mammalian IRES elements and that at least 10% of the translation of the gene product from the heterologous sequence is controlled by the activity of the IRES element, and spacer sequences between 25-7500 nucleotides in length. One would have been motivated to do so, given the suggestion by Polo et al. that the composition recombinant alphavirus replicon can be modified to control expression of genes. There would have been a reasonable expectation of success, given the knowledge that nucleic acid spacers ranging from 9-54 bases upstream of IRES elements can improve protein expression, as taught by Chappell et al., also given the knowledge that several IRES elements from mammalian viruses are known, as taught by Martinez-Salas et al., and also given the knowledge that alphavirus replicons can be generate to express alphavirus non-structural and structural proteins of which can also be mutated to generate attenuated phenotypes, as taught by Johnston et al. Even though the references discussed above do not disclose a specific percentage of controlled translation of a RNA sequence by IRES elements, one skilled in the art would be motivated to perform routine optimization of alphavirus replicons containing IRES elements in order to control gene expression, especially if toxicity is a concern by altering spacer length, activity of IRES elements, etc., see MPEP § 2144.05 (II) (A). Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubensky et al. as applied to claims 48-50 above, and further in view of Chappell et al. *Supra*.

The claimed invention as described above, also includes a spacer sequence upstream of the IRES element.

The teachings of Dubensky et al. are discussed above. However, Dubensky et al. do not teach the use of a spacer upstream of the IRES element.

Chappell et al. teach the use of various spacer lengths upstream of IRES elements in order to increase protein expression.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Dubensky et al. in order to generate a recombinant nucleic acid with a spacer sequence upstream of an IRES element. One would have been motivated to do so, given the suggestion by Dubensky et al. that the composition be modified to increase protein expression. There would have been a reasonable expectation of success, given the knowledge that introducing spacer sequences upstream of IRES sites can increase protein expression, as taught by Chappell et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polo et al. as applied to claims 58 and 59 above, and further in view of Chappell et al. *Supra*.

The claimed invention as described above is also drawn to a recombinant nucleic acid with a spacer nucleic acid sequence upstream of an IRES element.

The Teachings of Polo et al. are discussed above, however, Polo et al. do not teach introducing spacer sequences upstream of the IRES element.

Chappell et al. teach the use of various spacer lengths upstream of IRES elements in order to increase protein expression.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Polo et al. in order to generate a recombinant nucleic acid with a spacer sequence upstream of an IRES element. One would have been motivated to do so, given the suggestion by Polo et al. that the composition be modified to increase protein expression. There would have been a reasonable expectation of success, given the knowledge that introducing spacer sequences upstream of IRES sites can increase protein expression, as taught by Chappell et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-14, 16, 17, 19, 21, 23-36 and 58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicants mean by claiming a first, a second and/or a third nucleic acid sequence in claims 1 and 58. Is this to mean that the claimed recombinant nucleic acid is to contain these nucleic acids in this order, (i.e. first, second, third). If so, shouldn't the subgenomic promoter, IRES element and heterologous nucleic acid also be assigned a position? In addition, it is unclear how there can be "at least one second nucleic acid" since the any additional nucleic acid after the first two would be considered the third, fourth, fifth, etc. If this is meant to imply that multiple "second nucleic acids" might be present in the replicon, wouldn't this result in a second-second nucleic acid, a third-second nucleic acid, etc? Clarification is requested.

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Claim 35 recites the limitation "the population of claim 32" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 50. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 recites the same limitation that claim 29 states, which claim 30 depends from.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



/Benjamin P Blumel/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner
Art Unit 1648

Notice to Comply	Application No. 10/804,331	Applicant(s) Smith et al.	
	Examiner Benjamin Blumel	Art Unit 1648	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: The disclosure is missing SEQ ID NO:s, see attached Action under Objections.

Applicant Must Provide:

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
- ☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923

For CRF Submission Help, call (703) 308-4212 or 308-2923

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